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### REMARKS

Claims 1, 2, 5-11, 18, 23, and 26-29 are amended. Claims 1-68 are now pending in this application. The amendments to the claims are supported by the application as filed, and no new matter has been added.

#### I. The Drawings

The Examiner noted that Figure 2 of the originally-filed application is a color photograph. Applicants include herewith a petition for acceptance of the color photograph, the appropriate fee, three sets of color photographs, and an amendment to the specification regarding the use of the color photograph. Applicants believe that the conditions for acceptance of color drawings have been satisfied.

#### II. The 35 U.S.C. § 112 Rejection of the Claims

The Examiner rejected claims 1-26 under 35 U.S.C. § 112, second paragraph, alleging that those claims are indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Specifically, the Examiner alleged that claims 1, 5 and 18 are vague and indefinite. Claims 1 and 18 have been amended, thereby rendering this rejection moot as to claims 1 and 18.

The Examiner rejected claim 5, alleging that the term "random DNA" sequence is vague and indefinite because the metes and bounds of the term "random DNA" are unclear. This rejection is respectfully traversed.

The Examiner's attention is respectfully drawn to the specification, for example to page 16, lines 25-31 and to page 32, lines 3-9, where Applicants discuss "random" DNA sequences. At page 16, the specification teaches that "[r]andom DNA sequences can be inserted into the two-promoter plasmids to create a library of plasmids that will interfere with expression of specific genes. The library of plasmids can be introduced into cells to create random knockout phenotypes. Specific phenotypes can be selected and the gene responsible for generating the phenotype can be recovered by isolating the entire plasmid or by amplifying the DNA insert using the polymerase chain reaction (PCR) and primers specific to the promoter sequence." Also, at page 32, the specification teaches that "... the two-promoter approach is the first convenient random knockout technology in *T. brucei*

and forms the basis for genetic selection schemes that have not been practical to date." Applicants submit that the art worker, in possession of Applicants' specification, would readily understand the metes and bounds of claim 5 to be clear.

Thus, it is submitted that the pending claims are in conformance with the requirements of 35 U.S.C. § 112, second paragraph. Therefore, withdrawal of the rejections of the claims under 35 U.S.C. § 112, second paragraph, is appropriate and respectfully requested.

### III. The 35 U.S.C. § 102 Rejections of the Claims

The Examiner rejected claims 1, 5-6, 12-14, 16-17, 19 and 23-29 under 35 U.S.C. § 102(e), alleging that those claims are anticipated by Plaetinck *et al.* (US 2003/0061626). As this rejection may be maintained with respect to the pending claims, it is respectfully traversed.

As amended, independent claim 1 recites a double-stranded RNA (dsRNA) expression vector comprising (a) a double-stranded designated DNA sequence of interest comprising a DNA sequence from a protist; and (b) a pair of promoters on opposite ends of the designated DNA sequence, wherein the promoters are oriented towards each other and wherein each is capable of initiating transcription of a strand of the double-stranded DNA sequence into RNA in a cell. Claims 5-6, 12-14, 16-17, 19 and 23-29 depend either directly or indirectly from claim 1.

A rejection of anticipation under 35 U.S.C. § 102 requires the disclosure in a single prior art reference of each element of the claim under consideration. *In re Dillon*, 919 F.2d 688, 16 U.S.P.Q.2d 1897, 1908 (Fed. Cir. 1990) (en banc), cert. denied, 500 U.S. 904 (1991). For anticipation, there must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the art. *Scripps Clinic & Res. Found. v. Genentech, Inc.*, 927 F.2d 1565, 18 USPQ2d 101 (Fed. Cir. 1991). To overcome the defense of anticipation, "it is only necessary for the patentee to show some tangible difference between the invention and the prior art." *Del Mar Engineering Lab v. Physio-Tronics, Inc.*, 642 F.2d 1167, 1172, (9<sup>th</sup> Cir. 1981). Applicants respectfully submit that the claims are not anticipated by the cited document.

As the Examiner acknowledges at page 6 of the Office Action, Plaetinck *et al.* do not teach the use of their system in protozoan cells to target essential genes. Further, Plaetinck *et al.* do not teach a double-stranded RNA (dsRNA) expression vector comprising a DNA sequence from a protist. Accordingly, because Plaetinck *et al.* lacks the disclosure of each element of the claims

under consideration, withdraw of the rejection of the claims under 35 U.S.C. § 102 is appropriate and is respectfully requested.

#### IV. The 35 U.S.C. § 103 Rejections of the Claims

The Examiner rejected claims 2-4, 8-10, and 21-22 under 35 U.S.C. § 103(a), alleging that those claims are unpatentable over Plaetinck *et al.* in view of Ngo *et al.* (*PNAS*, 95, 14687-14692, 1998). As this rejection may be maintained with respect to the pending claims, it is respectfully traversed.

A rejection of obviousness under 35 U.S.C. § 103 requires that the Examiner establish a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness, the Examiner has the burden to establish three basic elements. First, the Examiner must establish that there is some suggestion or motivation, either in the cited documents themselves or in the knowledge generally available to an art worker, to modify the documents or to combine document teachings so as to arrive at the claimed invention. Second, the Examiner must establish that there is a reasonable expectation of success. Finally, the Examiner must establish that the prior art documents teach or suggests all the claim limitations. M.P.E.P. § 2143. Applicants respectfully submit that the claims are not *prima facie* obvious in view of the cited documents.

Applicants respectfully submit that the Examiner has not established that either the cited documents or the knowledge generally available to an art worker at the time the application was filed provides a suggestion or motivation to combine or modify the cited documents so as to arrive at Applicants' claimed invention. The teaching or suggestion to arrive at the claimed invention must be found in the prior art, not in Applicants' disclosure. M.P.E.P. § 2143 citing with favor, *In re Vaeck*, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991); *emphasis added*. The Examiner must provide specific, objective evidence of record for a finding of a suggestion or motivation to combine the reference teachings and must explain the reasoning by which the evidence is deemed to support such a finding. *In re Sang Su Lee*, 277 F.3d 1338, 61 U.S.P.Q.2D 1430 (Fed. Cir. 2002); *emphasis added*. Mere conclusory statements do not fulfill the Examiner's burden. *Id.*; *emphasis added*

Applicants respectfully assert that the Examiner has not provided appropriate evidence or explanation for a suggestion or motivation to combine the cited documents. Instead, in the Office Action mailed July 15, 2003, the Examiner alleges that the art worker would have been motivated to

combine the cited references “to receive the expected benefit of being able to inducibly express dsRNAs targeted to different genes in *T. brucei* in an inducible fashion in order to characterize their gene function” (page 7 of the Office Action). However, the references themselves must provide the motivation. Thus, Applicants respectfully assert that the claims are not *prima facie* obvious in view of the cited documents at least because the Examiner has not provided appropriate evidence or explanation for a suggestion or motivation to combine the cited documents. Accordingly, withdraw of the rejection of the claims under 35 U.S.C. § 103 is appropriate and is respectfully requested.

#### V. Claims Free of the Prior Art

The Examiner rejected claims 1, 5-6, 12-14, 16-17, 19 and 23-29 under 35 U.S.C. § 102(e) and rejected claims 2-4, 8-10, and 21-22 under 35 U.S.C. § 103(a). The Examiner did not reject claims 7, 11, 15, 18, or 20 under 35 U.S.C. § 102 or § 103. Thus, Applicants presume that claims 7, 11, 15, 18, and 20 are free from the prior art.

**CONCLUSION**

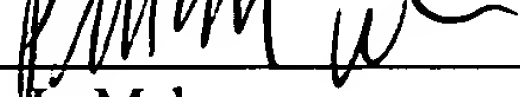
Applicants respectfully submit that the claims are in condition for allowance and notification to that effect is requested. The Examiner is invited to telephone Applicants' attorney (612-371-2110) to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,  
DOUGLAS J. LACOUNT ET AL.  
By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.  
P.O. Box 2938  
Minneapolis, MN 55402  
(612) 371-2110

Date 1-15-04

By   
Peter L. Malen  
Reg. No. 44,894

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 15 day of January, 2004.

**Candis B. Buending**

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